



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2024/00708**

10 December 2024

Dear [REDACTED],

Thank you for your Freedom of Information (Fol) request received on 13 November. You wrote:

“May I know on which dates the following companies/applicants:

- * made requests for authority to distribute Covid-19 vaccines for the years 2021 - to date (13 November 2024)*
- * each individual company/applicant was granted authority.*

*Spikevax (Moderna)
Comirnaty (Pfizer/BioNTech)
Nuvaxovid (Novavax)
Vaxzevria (AstraZeneca/Oxford)
Janssen COVID-19 Vaccine (Johnson & Johnson)
Valneva (Valneva)”*

MHRA Response

Following a search of our paper and electronic records, we have established that the information you requested is not held by this Agency. We do not hold dated requests for distribution of the Covid-19 vaccines per se.

Advice and assistance

Applicants submit applications for medicines to MHRA for consideration, in terms of the COVID-19 vaccines, applying by way of temporary authorisation under Regulation 174 and later in most cases for conditional or full Marketing Authorisations. There are many different COVID-19 vaccines authorised from the companies which you have listed in your request and within the time-period specified. For example, there are often separate marketing authorisations for later variants of SARS-CoV-2.

The information we hold

There is a very considerable amount of information about the COVID-19 vaccines in the public domain. In terms of dates of grant for the Regulation 174, conditional, or Marketing Authorisations these should be available in the public assessment reports which can be located on [MHRA Products | Home](https://www.mhra.gov.uk/products). However, a granted marketing authorisation and its grant date would not be considered a date of the ‘requests for authority to distribute’. Please note, Companies must separately also notify the MHRA of the marketing status of their products, however, similarly such notifications do not represent ‘requests for authority to distribute’, rather it is a combination of steps / processes which need to be in place.

Regulation 174 letters

For the Pfizer/BioNTech COVID-19 vaccine, a process was in place. This has been summarised as follows. MHRA issued 'No objection' letters to the company, i.e. stating that MHRA has no objection to the certification and to the release of a batch or batches of vaccine. These letters tended to be batch specific but some cover multiple batches. Once an administrative step of the Applicant/MAH providing a certificate of conformance to MHRA has been completed shipment of the specific batch could proceed. This could be considered a date of authority to distribute the product. However, this is not a terminology we use. In addition, due to the number of dated letters we expect to hold, this is unlikely to be the intended meaning of your request?

MHRA batch release (formerly through NIBSC).

The below webpage explains how MHRA conduct independent batch testing of vaccines. At the end of the batch testing process provided the results for the batch comply with the agreed specifications a certificate is sent to the manufacturer. The date the manufacturer made each request to NIBSC for batch certification could be understood to mean 'requests for authority to distribute Covid-19 vaccines'. However, as mentioned above this is not a regulatory terminology.

[NIBSC - Independent batch release testing at the NIBSC](#)

Information on deployment of Moderna vaccine

The [Moderna COVID-19 vaccine](#) was also authorised under R174 (and subject to conditions under R174A) on 8 January 2021, however no Moderna supply was provided under R174A. Supply of the Moderna vaccine was not anticipated until early April 2021, by which time a Great Britain (GB) conditional marketing authorisation (CMA) for the Moderna vaccine was in place, issued by the MHRA on 31 March 2021. This CMA was put in place via the European Commission Decision Reliance Procedure, following an application from Moderna on 27 March 2021. All supply of Moderna in GB was deployed under the CMA, and Northern Ireland (NI) supply was under the [European Medicines Agency \(EMA\) CMA](#), issued on 6 January 2021 (the issue of regulatory divergence between NI and GB is explained below).

Source: [Regulations 174A and 247A: one-year review - GOV.UK](#)

Conclusion

If you wish to make a new request for information, please specify:

- The name of the vaccine/s that are of interest to you, the name should enable us to discern if these are variant vaccines, alternatively PL numbers can be provided. As you can observe from the above the regulatory process can vary based on the form of the application made. Therefore, it may be best to reduce to the request to a single vaccine as then we could likely provide you with a detailed regulatory timeline.
- If it is the date that the first temporary authorisation under regulation 174 occurred, and/or the same for the conditional or marketing authorisation/s
- Should a new FOI request intend to relate to a date/s the applicant/s submitted the application/s to MHRA, please state as such.
- If your request relates to the dates of batch certification from NIBSC/MHRA please be advised that due to the number of batches certificated, we could not guarantee that such a request would not exceed the cost threshold under Section 12 of the FOIA.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](https://ico.org.uk/for-the-public/foi/) or telephone 0303 123 1113.

Re-use of our information

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>